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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,552	03/11/2005	Hubert Kurnsteiner	IB/G-32677A	9558
72554	7590	11/30/2007		
SANDOZ INC 506 CARNEFIE CENTER PRINCETON, NJ 08540			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 11/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,552	<b>Applicant(s)</b> KURNSTEINER ET AL.	
	<b>Examiner</b> Malgorzata A. Walicka	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-6,8-15 and 17-21 is/are allowed.
- 6) ☒ Claim(s) 2, 7, 16 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The amendment of Sept. 24, 2007 is acknowledged. Claims 1-2, 4-7 and 9-12 have been amended. Claims 1-22 are pending and under examination.

## **DETAILED ACTION**

Objections and rejections made in the Office action of June 22, 2007 that are not repeated herein are withdrawn.

### **Rejections**

#### **35 USC 112 second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 16 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the transitional phrase "consisting essentially of" which is unclear absent the appropriate definition in the disclosure. For examination purposes "consisting essentially of" is treated as the open phrase "comprising"; see MPEP 2111.03.

Claim 16 is rejected because it is not clear whether a host cell is in the body of larger organism or it is an isolated host cell.

#### **Response to applicants' arguments**

In their REMARKS, page 6, paragraphs two and three, applicants present their opinion

"A person having ordinary skill in the art would likewise recognize that the scope of the claim 7 encompasses nucleic acid molecules having the nucleotide sequence of SEQ ID NO: 2, SEQ ID NO: 3, or SEQ ID NO: 4 with the possibility of additional or different nucleotides only to the extent that they do not materially alter the basic and novel characteristics and function of encoding a protein expressed therefrom (see

above). As already noted, a person having ordinary skill in the art would have no trouble understanding the nature and scope of permissible changes to the claimed nucleic acid sequences and it is within the ordinary skill of the art to identify and distinguish non-material changes in the nucleotide sequences."

Applicants' arguments have been fully considered but is found not persuasive for the following reasons.

1. It is not clear what is meant by "to materially alter".
2. It is not clear what is meant by "basic characteristic ~~characteristic~~".
3. It is not clear what is meant by "permissible changes to the claimed nucleic acid sequences", which are to be understandable for a person skilled in the art.
4. Neither applicants' in their REMARKS or the disclosure teaches how to distinguish non-material from material changes in the nucleotide sequences.

In addition applicants argue;

"A person having ordinary skill in the art would likewise recognize that the scope of the claim 22 encompasses a protein having the amino acid sequence of SEQ ID NO: 1, with the possibility of additional or different amino acids only to the extent that they do not materially alter the basic and novel characteristics and function of the protein defined by SEQ ID NO: 1 (which are set out in the specification) (see above). Examples include substitution by homologous amino acids that do not alter the essential hydrophobic/hydrophilic and/or charge and/or secondary or tertiary structure of the protein, leader or signal sequences or other sequences removed posttranslationally. See, e.g. specification, pages 5, first and second full paragraphs and page 6, first & fourth full paragraphs".

Applicants' arguments relate basically to variants of the claimed sequences, which are not described or claimed. The description given on the quoted passages is related to substitutions resulting from degeneracy of genetic code. The claims do not contain the limitations present in the quoted

passages, and the most importantly, none of description of pages 5, first and second full paragraphs and page 6, first & fourth full paragraphs is defining the phrase "consisting essentially of".

In summary, one of skills in the art does not know what is the meaning of the transitional phrase "consisting essentially of". The claims are therefore rejected. Applicants are suggested to amend claims 2, 7 and 22 so that they recite "consisting of" to place the claims in conditions for allowance.

Furthermore Applicants emphasize that the term

"A 'host cells' is understood in the art to mean any cell that is transformed with an exogenous nucleic acid molecule. Though the Patent Office raises an interesting scientific point as to whether such a host cell might be in the body of the larger organism, as opposed to being grown in culture, this has no bearing on the clarity or definiteness of the claim", REMARKS, paragraph bridging page 6 and 7.

Applicants position has been considered, but is found not persuasive. The use of the terms "a host cell" vs. "an isolated host cell" is not a scientific point, but the question of scope that is indefinite in case of use of the term "host cell" when the disclosure is not describing and enabling any organism comprising the host cell. In result claim 16 remains rejected.

### **35 USC 112 first paragraph**

#### **Written description**

Claims 2, 7 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 7 and 22 are rejected as containing new matter. The disclosure as filed does not contain the phrase "consisting essentially of".

#### **Response to applicants' argument**

Regarding rejection of claims 2, 7 and 22, Applicants' positions is that "consisting essentially of" specifically-defined sequences is amply supported by the specification disclosure", page 8 of REMARKS, fist paragraph.

Applicants' argument does not seem to be persuasive. The term "consisting essentially of" requires a definition, not a support. This is a question of description and scope of invention. The term does not exist in the disclosure as filed. It was introduced to the claims in the preliminary amendment of March 11, 2005. **Originally filed claims recite "comprising" and "exclusively consisting of ", which is an equivalent of "consisting of".**

## CONCLUSION

Claims 1, 3-6, 8-15, 17-21 are allowed for the reasons stated in the previous action. Claims 2, 7, 16 and 22 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by

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telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.  
Art Unit 1652  
Patent Examiner



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